



**UNITED STATES DEPARTMENT OF COMMERCE**  
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/709,477 11/13/00 PREUILH

I 2365-23

HM12/1003

NIXON & VANDERHYE P C  
8TH FLOOR  
1100 NORTH GLEBE ROAD  
ARLINGTON VA 22201-4714

EXAMINER

WELLS, L

ART UNIT

PAPER NUMBER

1619

DATE MAILED:

10/03/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

**Office Action Summary**

Application No.

09/709,477

Applicant(s)

PREUILH ET AL.

Examiner

Lauren Q Wells

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 31-61 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 31-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claims \_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. § 119**

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☒ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

**Attachment(s)**

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6.
- 18) ☐ Interview Summary (PTO-413) Paper No(s) \_\_\_\_.
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other: \_\_\_\_\_

## **DETAILED ACTION**

### ***Priority***

Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on June 19, 1998. It is noted, however, that applicant has not filed a certified copy of the French application as required by 35 U.S.C. 119(b).

### ***Specification***

The abstract of the disclosure is objected to because it is illegible—the print is very tiny and the ink quality is poor. A new abstract is respectfully requested. See MPEP § 608.01(b).

The title of the invention is not descriptive. A new title is required that is clearly indicative of the invention to which the claims are directed.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 32, 33, 40, 50-53, and 59 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(i) A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by

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raising a question or doubt as to whether the feature introduced by such language is (a) merely exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 32 (line 4) recites the broad recitation "clobetasol propionate", and the claim also recites "clobetasol 17-propionate" which is the narrower statement of the range/limitation.

(ii) The term "derivative" in claims 40 (line 2), 52 (line 5), and 53 (line 2) is vague and indefinite, as it is not clear what other compounds are encompassed by this term. The specification does not define this term and one of ordinary skill in the art would not be appraised of it.

(iii) Claims 50 and 51 are vague and indefinite, as it is not clear what ratio is being claimed. Is the active material:anionic surfactant ratio and active material:amphoteric surfactant ratio being claimed? Is the anionic surfactant:amphoteric surfactant ratio being claimed?

(iv) The term "thickened" in claim 59 (line 2) is a relative term which renders the claim indefinite. The term "thickened" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

(v) The phrase "retinol derivative" in claim 33 (line 2) is vague and indefinite, as it is not clear what are compounds this phrase encompasses.

*Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 31-61 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron (4,722,837) in view of Casmer et al. (3,984,544) and Klingman (5,998,395) in further view of Cauwet et al. (5,661,118).

Cameron teaches a medicated shampoo composition comprising 0.1-0.5% hydrocortisone, 20-35% detergent, 1-6% thickener, preservative, and other ingredients, wherein the detergent can be a combination of sodium lauryl sulfate and coamidopropyl betaine. The reference fails to teach retinoids, propenetrating agents, cationic polymers, nonionic surfactant, ceramide, and glycoceramide. See Col. 1, line 5-Col. 6, line 35.

Casmer et al. teach retinoic acid esters of steroids of the pregnane series, and their use in treating acne vulgaris. Disclosed is a solution comprising prednisolone 21-retinoate and isopropyl alcohol. See Col. 1, line 30-Col. 2, line 60; Col. 5, line 5-Col. 11, line 6; Col. 31, line 53-Col. 36, line 67.

Kligman teach methods of treating inflammatory dermatosis. Disclosed are compositions comprising a combination of clobetasol propionate or triamcinolone acetonide or hydrocortisone and tretinoin, wherein the corticosteroid comprises 0.00001-3% of the composition and the retinoid comprises 0.00001-3% of the composition. It is disclosed that these compounds work synergistically. The compositions are disclosed as taking on various forms, such as creams, dressings, gels, lotions, ointments, or liquids. Further examples of suitable retinoids disclosed include retinyl palmitate and retinyl propionate. See Col. 1, line 19-Col. 12, line 20.

Cauwet et al. teach hair and skin washing and treatment compositions based on ceramide and/or glycosphingolipid and cationic polymers. Disclosed is a composition comprising sodium lauryl ether sulphate, cocoylbetaine, ceramide A, and guar hydroxypropyltrimonium chloride. Nonionic surfactants are disclosed as constituents that may be especially contained within the composition. See Col. 13, line 1-Col. 20, line 65.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Cameron using the teachings of Casmer et al. and Kligman et al. and obtain a composition comprising both a corticosteroid and a retinoid, isopropyl alcohol, sodium lauryl sulfate, and cocamidopropyl betaine because a) Cameron, Casmer et al., and Kligman et al. all teach compositions for treating dermatological inflammatory conditions; b) Cameron, Casmer et al., and Kligman et al. all teach corticosteroids as active agents; c) Cameron and Kligman et al. both teach compositions for the treatment of seborrhea; d) Kligman et al. and Casmer et al. both teach compositions for the treatment of acne vulgaris; e) Kligman et al. teach corticosteroids and retinoids as having a synergistic effect when placed in a composition to treat inflammatory dermatosis. Further, it would have been obvious to one of

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ordinary skill in the art at the time the invention was made to have modified the composition of the combined references using the teachings of Cauwet et al. and obtain a composition comprising both a corticosteroid and a retinoid, isopropyl alcohol, sodium lauryl sulfate, cocamidopropyl betaine, ceramide, glucoceramide, anionic surfactant, and guar hydroxypropyltrimonium chloride because a) the combined references and Cauwet et al. all teach dermatological cosmetic compositions for topical application; b) Cameron teaches the composition for treating dandruff and Cauwet et al. teach anti-dandruff agents as constituents in the composition; c) Cameron and Klingman et al. both teach compositions for treating seborrhea and Cauwet et al. teach anti-seborrhea agents as constituents in the composition.

The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

#### *Comments/Notes*

Examiner respectfully suggests that Claim 42 be amended. It is suggested that the large gap between the words "cocamidopropyl" and "betaines" be removed, and it is further suggested that a comma be inserted following the word "hydroxysultaine"

#### *Prior Art*

The prior art made of record and not specifically relied upon in any rejections cited above is either 1) considered cumulative to the prior art that was cited in a rejection or is 2) considered pertinent to the applicant's disclosure and shows the state of the art in its field but is not determined by the Examiner to read upon the invention currently being prosecuted in this application.


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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lauren Q Wells whose telephone number is (703) 305-1878. The examiner can normally be reached on M-F (7-4:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Diana L Dudash can be reached on (703) 308-2328. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and (703) 308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

lqw  
July 3, 2001



**DAMERON L. JONES**  
**PRIMARY EXAMINER**